THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:20-cv-00098-MR

TED JACKSON OWEN,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**MEMORANDUM OF**
	)	**DECISION AND ORDER**
FDA OFFICE OF GENERIC DRUGS, *et al.,*	)	
	)	
	)	
Defendants.	)	
	)	

THIS MATTER is before the Court on the Plaintiff's "Notice of Substitution of the United States as the Sole Party Defendant and Motion to Amend Caption" [Doc. 12] and the United States' Motion to Dismiss [Doc. 13].

I. PROCEDURAL BACKGROUND

On April 20, 2020, Ted Jackson Owen (the "Plaintiff"), proceeding *pro se*, initiated this action against the Food and Drug Administration (the "FDA") Office of Generic Drugs and several FDA employees, including Former FDA Acting Commissioner Dr. Norman Sharpless, Dr. Howard Chazin, and Debra M. Catterson (collectively, the "Individual Defendants"). [Doc. 1 at 2]. The

Complaint asserts a claim under the Federal Tort Claims Act ("FTCA") stemming from a heart attack the Plaintiff suffered in 2013. [Doc. 1 at 2].

On December 1, 2020, the United States filed the present "Notice of Substitution of the United States as the Sole Party Defendant and Motion to Amend the Caption" (the "Motion to Substitute and Amend"). [Doc. 12]. The United States also filed a Motion to Dismiss on behalf of all the Defendants. [Doc. 13]. The Plaintiff has filed a response to the Motion to Dismiss. [Doc. 16]. The United States has filed a reply. [Doc. 17].[1]

Having been fully briefed, this matter is ripe for disposition.

II. STANDARDS OF REVIEW

A. Rule 12(b)(1) Standard

A motion to dismiss made pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure addresses whether the court has subject-matter jurisdiction to hear the dispute. See Fed. R. Civ. P. 12(b)(1). Where a defendant contends that a complaint fails to allege facts upon which the Court can base subject matter jurisdiction, the Court must assume as true the factual allegations in the complaint. Adams v. Bain, 697 F.2d 1213, 1219 (4th Cir. 1982). The burden of establishing subject matter jurisdiction on a

[1] The Plaintiff also moved to file an Ex Parte Surreply on March 22, 2021. [Doc. 18]. The Court denied that Motion on March 30, 2021. [Doc. 19].

motion to dismiss rests with the party asserting jurisdiction. Id.; Williams v. United States, 50 F.3d 299, 304 (4th Cir. 1995).

B. Rule 12(b)(6) Standard

The central issue for resolving a Rule 12(b)(6) motion is whether the claims state a plausible claim for relief. See Francis v. Giacomelli, 588 F.3d 186, 189 (4th Cir. 2009). In considering such a motion, the Court accepts the plaintiff's allegations as true and construes them in the light most favorable to the plaintiff. Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 253 (4th Cir. 2009); Giacomelli, 588 F.3d at 190-92. When considering a motion to dismiss, the Court is obligated to construe a *pro se* complaint liberally, "however inartfully pleaded[.]" Booker v. S.C. Dep't of Corr., 855 F.3d 533, 540 (4th Cir. 2017), cert. denied, 138 S. Ct. 755, 199 L. Ed. 2d 604 (2018) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)).

Although the Court accepts well-pled facts as true, the Court is not required to assume the truth of "bare legal conclusions." Aziz v. Alcolac, Inc., 658 F.3d 388, 391 (4th Cir. 2011). "The mere recital of elements of a cause of action, supported only by conclusory statements, is not sufficient to survive a motion made pursuant to Rule 12(b)(6)." Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012).

The claims need not contain "detailed factual allegations," but must contain sufficient factual allegations to suggest the required elements of a cause of action. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Consumeraffairs.com, 591 F.3d at 256. Namely, the complaint is required to contain "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Consumeraffairs.com, 591 F.3d at 255. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); see also Consumeraffairs.com, 591 F.3d at 255. The mere possibility that a defendant acted unlawfully is not sufficient for a claim to survive a motion to dismiss. Consumeraffairs.com, 591 F.3d at 256; Giacomelli, 588 F.3d at 193. Ultimately, the well-pled factual allegations must move a plaintiff's claim from possible to plausible. Twombly, 550 U.S. at 570; Consumeraffairs.com, 591 F.3d at 256.

III. FACTUAL BACKGROUND

Viewing the well-pled factual allegations in the Complaint as true, the following is a recitation of the relevant facts.

For roughly six years, the Plaintiff took the prescription drug Imitrex. [Doc. 1 at 6]. In December 2013, the Plaintiff began taking Sumatriptan, a

generic version of Imitrex manufactured by Dr. Reddy's Laboratories ("Dr. Reddy's"). [Id.]. On December 20, 2013, the Plaintiff experienced chest pains and had a heart attack. [Id.].

On December 29, 2016, the Plaintiff sued Dr. Reddy's in Transylvania County Superior Court, claiming that the Sumatriptan caused his heart attack. [Doc. 14-6 at 1]. On February 1, 2017, Dr. Reddy's removed the case to this Court. [Id.]. [2]

In June 2017, the Plaintiff submitted one of his Sumatriptan tablets to an independent laboratory for testing. [Doc. 14-9 at 7]. In July 2017, the Plaintiff sent three tablets to the FDA "requesting an analysis of these pills because each time [he] took one of this lot of medication [he] suffered chest pains." [Doc. 1 at 7]. The Plaintiff further stated that "[i]t is important to me to test this drug for any inconsistenc[ies] or release variations or any other differences." [Id.]. The Plaintiff submitted the independent laboratory testing results to the FDA in September 2017. [Doc. 1-1 at 26, 28]. On December 15, 2017, the FDA emailed the Plaintiff that they had used "highly sophisticated, state-of the art technology" to compare the Plaintiff's tablets

[2] The prior case number was Civil Case No. 1:17-cv-00037-MR-DLH. For ease of citation, the Court cites to the documents from that case that are attached to the United States' Motion to Dismiss.

to other approved tablets available on the marketplace and that the "results from all samples showed no identifiable differences." [Doc. 1-1 at 24].

On December 13, 2017, the Magistrate Judge issued a Memorandum and Recommendation recommending that the Court grant Dr. Reddy's Motion for Judgment on the Pleadings. [Doc. 14-6]. On February 2, 2018, this Court accepted the Magistrate Judge's Memorandum and Recommendation, granted Dr. Reddy's Motion for Judgment on the Pleadings, and dismissed the case with prejudice. [Doc. 14-7].

On April 20, 2020, the Plaintiff filed the present action. [Doc. 1].

IV. DISCUSSION

A. Motion to Substitute United States for Individual Defendants

"The Federal Employees Liability Reform and Tort Compensation Act of 1988, commonly known as the Westfall Act, accords federal employees absolute immunity from common-law tort claims arising out of acts they undertake in the course of their official duties." Osborn v. Haley, 549 U.S. 225, 229 (2007) (citing 28 U.S.C. § 2679(b)(1)). Once the Attorney General of the United States, or a United States Attorney, certifies that the defendant employees were "acting within the scope of their employment at the time of the incident out of which the claim arose," the United States is substituted as the defendant and the individual employees are dismissed from the action.

Doe v. Meron, 929 F.3d 153, 160 (4th Cir. 2019); 28 U.S.C. § 2679(d)(1). If a plaintiff fails to challenge the certification submitted by the Attorney General or a United States Attorney, "the certification is conclusive." Meron, 929 F.3d at 160.

Here, the United States has provided a Certification of Scope of Employment from the United States Attorney, which states that "with respect to the events alleged in the Complaint, which allegations are denied for purposes of assessing liability, Defendants Dr. Howard Chazin, Debra M. Catterson and Norman Sharpless, MD, employees of the United States, were acting at all relevant times within the course and scope of their federal employment." [Doc. 12 at 6; Doc. 14-11]. The Plaintiff has not opposed the Motion to Substitute or challenged the Certification. Accordingly, the United States will be substituted for the Individual Defendants, and the Individual Defendants will be dismissed as parties. See Meron, 929 F.3d at 160.

B. Motion to Dismiss by the FDA Office of Genetic Drugs

Sovereign immunity protects the United States and its agencies from suit absent a waiver of immunity. FDIC v. Meyer, 510 U.S. 471, 475 (1994); Welch v. United States, 409 F.3d 646, 650 (4th Cir. 2005). The FTCA "provides a limited waiver of sovereign immunity for civil actions against the United States." Seaside Farm, Inc. v. United States, 842 F.3d 853, 857 (4th

Cir. 2016) (citing 28 U.S.C. §§ 1346(b)(1), 2674). In FTCA suits, however, the United States is the only proper defendant—not any government agency or employee. See 28 U.S.C. § 2679(a); Smith v. United States, 561 F.3d 1090, 1099 (10th Cir. 2009) ("The United States is the only proper defendant in an FTCA action."). Because the Plaintiff cannot bring his FTCA claims against any party other than the United States, the FDA Office of Genetic Drugs will be dismissed as a defendant.[3]

C. Motion to Dismiss by the United States

The United States argues that the Plaintiff's claims relating to the FDA's approval of Sumatriptan are barred by sovereign immunity. [Doc. 14]. The United States further argues that the Plaintiff's other claims regarding any testing or misrepresentations by the FDA fail to state a claim upon which relief can be granted. [Id.].

1. Discretionary Function Exception

The FTCA waives the United States' immunity with respect to civil actions for injuries "caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment." 28 U.S.C. § 1346(b). The waiver of immunity does not

[3] Although the claims remaining are against the United States, the Court refers to the FDA where necessary for ease and clarity.

apply, however, to "[a]ny claim . . . based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." Id. § 2680(a). Federal courts thus "lack jurisdiction over claims falling within the discretionary function exception." Seaside Farm, Inc. v. United States, 842 F.3d 853, 858 (4th Cir. 2016); Williams v. United States, 50 F.3d 299, 304-05 (4th Cir. 1995). "FTCA plaintiffs have the burden of showing that the discretionary function exception does not foreclose their claim." Seaside Farm, 842 F.3d at 857.

Determining whether the discretionary function exception applies is a two-part test. Courts first must ascertain whether the action involved an element of choice or judgement by the agency. Wood v. United States, 845 F.3d 123, 128 (4th Cir. 2017). "When a statute, regulation, or policy *prescribes* the employee's conduct, the conduct cannot be discretionary and thus is unprotected by the discretionary function exception." Id. (emphasis in original). Second, the courts "must determine whether the challenged 'governmental actions and decisions' were 'based on considerations of public policy.'" Ayala v. United States, 982 F.3d 209, 214 (4th Cir. 2020) (quoting Berkovitz v. United States, 486 U.S. 531, 537 (1988)). When statutes, regulations, or agency guidelines permits discretion, "it must be

presumed that the agent's acts are grounded in policy when exercising that discretion." United States v. Gaubert, 499 U.S. 315, 324 (1991). The court does not "inquire whether policy considerations *were actually* contemplated in making a decision." Smith v. Wash. Metro. Area Transit Auth., 290 F.3d 201, 208 (4th Cir. 2002) (emphasis in original). Instead, "[t]he relevant inquiry is whether the decision 'in an objective, or general sense, . . . is one which we would expect inherently to be grounded in considerations of policy.'" Seaside Farm, 842 F.3d at 858 (quoting Baum v. United States, 986 F.2d 716, 721 (4th Cir. 1993)). If so, "it must be presumed that the agent's acts are grounded in policy when exercising that discretion." United States v. Gaubert, 499 U.S. 315, 324 (1991).

Applying the two-step framework, the Court considers first whether the FDA's conduct involved an element of choice or whether any federal statute, regulation, or policy prescribed necessary conduct in this circumstance. See Berkovitz, 486 U.S. at 536. "The FDA is the agency charged with approving all new and generic drugs for market." AstraZeneca Pharms. LP v. Food & Drug Admin., 872 F. Supp. 2d 60, 62 (D.D.C. 2012) (citing 21 U.S.C. § 355(a)); see also 21 C.F.R. § 355(d)(7). While the FDA follows regulations when determining whether to approve a particular drug, those regulations do not "specifically prescribe a course of action for [the FDA] to follow."

Berkovitz v United States, 486 U.S. 531, 536 (1988). As such, the application of those "regulations still involve[s] the exercise of discretion by the FDA." Bailey v. Eli Lilly Co., 607 F. Supp. 660, 662 (M.D. Pa. 1985) (citing Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978)). The Plaintiff does not cite any statutes or regulations which eliminate the FDA's discretion in the drug approval process. Accordingly, the Court concludes that the FDA's decision to approve certain drugs, including Sumatriptan, involves a choice or judgment by the agency. See, e.g., Forsyth v. Eli Lilly & Co., 904 F. Supp. 1153, 1160 (D. Haw. 1995) (holding that "[c]learly" the FDA "employees have discretion to determine what methods of testing are reasonably applicable for a given drug, whether the testing performed by the manufacturer was adequate and whether adequate methods and facilities are used for manufacturing the drugs").

The Court must next consider the second part of the two-step framework, which asks whether the judgment of the FDA was "of the kind that the discretionary function exception was designed to shield." Gaubert, 499 U.S. 315, 322–23. The FDA is charged with ensuring that products are safe and effective for their intended use after consideration of the "public policy such as the public's need for new drugs and the public's interest in safe and effective drugs." Forsyth, 904 F. Supp. at 1160; Gray v. United

States, 445 F. Supp. 337 (S.D. Tex. 1978). Because the FDA bases its decisions to approve certain drugs on public policy considerations, those decision cannot be the subject of an FTCA claim. King v. United States Fed. Drug Admin., 35 F. App'x 511, 514 (9th Cir. 2002) (holding that "FDA decisions concerning pre-market approval of medical devices" are the type of policy judgments "that the discretionary function exception exists to protect"). Accordingly, the Court concludes that the FDA's decision to approve certain drugs, including Sumatriptan, is of the type that discretionary function exception was designed to shield.

Because the two-prongs of the discretionary function exception are met here, the United States has not waived its sovereign immunity on the Plaintiff's claims regarding the FDA's approval of Sumatriptan.[4] See Bailey, 607 F. Supp. at 661-62 (explaining that sovereign immunity barred a negligence claim stemming from the FDA's decision to approve a drug that may have caused an injury because the approval of drugs constitutes a

[4] Even if the FDA had abused its discretion by negligently approving Sumatriptan, "[t]he discretionary function exception applies regardless of 'whether or not the discretion involved be abused,' and 'even if the discretion has been exercised erroneously.'" Pornomo v. United States, 814 F.3d 681, 689 (4th Cir. 2016) (quoting 28 U.S.C. § 2680(a) then Holbrook v. United States, 673 F.3d 341, 350 (4th Cir. 2012)).

discretionary function). Accordingly, the Court lacks subject-matter jurisdiction over that claim.[5]

2. Failure to Provide Certain Testing Results

The Plaintiff also seems to argue that the FDA is responsible for the dismissal of his prior lawsuit against Dr. Reddy's because he sent the FDA pills for testing and the FDA failed to send him the "test result information that [he] needed to support [his claim]" against Dr. Reddy's. [Doc. 1 at 6]. While the Plaintiff does not expressly state a legal cause of action, the Court construes the Plaintiff as seeking to raise a claim of negligence based on the FDA failing to provide him with certain test results. [Id.].

"An action [for negligence] under the FTCA may only be maintained if the Government would be liable as an individual under the law of the state where the negligent act occurred." Kerns v. United States, 585 F.3d 187, 194 (4th Cir. 2009) (citing 28 U.S.C. § 1346(b)(1)). When a claim for negligence has been asserted, the Court must first determine, as a matter of law, whether the defendant owed a duty of care to the plaintiff. Durden v. United States, 736 F.3d 296, 301 (4th Cir. 2013). "No legal duty exists unless the

[5] The United States further argues that the Plaintiff's FTCA claims regarding the approval of Sumatriptan are barred by the statute of limitations. [Doc. 14 at 9]. Having concluded that the Court lacks subject-matter jurisdiction over that claim, the Court has no jurisdiction to address the statute of limitations issue.

injury to the plaintiff was foreseeable and avoidable through due care." Stein, 360 N.C. at 328, 626 S.E.2d at 267 (citing Estate of Mullis v. Monroe Oil Co., 349 N.C. 196, 205, 505 S.E.2d 131, 137 (1998)). "If no duty exists, there logically can be neither breach of duty nor liability." Harris v. Daimler Chrysler Corp., 180 N.C. App. 551, 555, 638 S.E.2d 260, 265 (2006).

The Plaintiff has failed to assert sufficient facts demonstrating that the FDA owed him a duty of care on which to base a negligence claim. While the FDA agreed to test the Plaintiff's pill, the FDA never agreed to go beyond its traditional testing procedure and provide the Plaintiff with a laboratory analysis to support his lawsuit against Dr. Reddy's. The FDA did not create a duty to the Plaintiff by agreeing to test his pills in accordance with its obligation to protect the public and ensure the safety of generic drugs. The Plaintiff seems to assert that the FDA had some duty to serve in an expert capacity for him in his suit against Dr. Reddy's. The FDA, however, has no such obligation. Because the Plaintiff has failed to show that the FDA owed him a duty of care, he cannot establish a negligence claim against the FDA for failing to provide him with certain information about the pills he sent to the FDA for testing.[6]

[6] The Court notes that the United States has disclosed that the Plaintiff is currently engaged in a Freedom of Information Act request. The Court makes no finding as to the viability of that request or as to the right the Plaintiff may have to the information he seeks.

Even if the FDA had owed the Plaintiff a duty of care, the FDA's actions are not sufficient to support a negligence claim. The FDA tested the Plaintiff's pills and concluded that there were "no identifiable differences" between the Plaintiff's pills and the other approved Sumatriptan products on the market. Because the FDA did not find any issues with the Plaintiff's pill, the FDA testing could not have affected the speculative nature of the Plaintiff's claims in his lawsuit against Dr. Reddy's, which was the reason that those claims were dismissed. [Doc. 14 at 21].

While the Plaintiff seems to fault the FDA for failing to identify the reason for his heart attack, the FDA specifically explained that its testing was "limited in scope" and that it could not identify the cause of every individual's health problems. The Plaintiff may wish that the FDA testing had revealed support for his claim against Dr. Reddy's, but that does not create a basis for a negligence claim. The Plaintiff has presented no plausible allegation to establish that the FDA performed its testing negligently or otherwise engaged in conduct that could support a negligence claim.[7]

[7] Although the Plaintiff also seems to argue that the FDA should be held liable because it "destroyed [his] pills" during the testing [Doc. 1 at 6], the testing that the Plaintiff requested necessarily required the pills to be destroyed. It was not negligent for the FDA to destroy the Plaintiff's pills in the process of performing the testing that he requested.

In short, the Plaintiff has offered no basis upon which the Court could conclude that the FDA owed him a duty of care. Even if the Plaintiff had established that the FDA had such a duty, he has not made any plausible allegations to demonstrate a breach of such duty. Accordingly, the Plaintiff's claims regarding the testing performed by the FDA will be dismissed.

3. Failure to Provide Truthful Information

While the Plaintiff also claims that the FDA has "not been truthful or forthcoming" and that the FDA "has covered up for Dr. Reddy's Laboratories[,]" [Doc. 1 at 7], the FTCA does not waive sovereign immunity for "[a]ny claim arising out of . . . misrepresentation, [or] deceit." 28 U.S.C. § 2680(h). To the extent that the Plaintiff makes any claims based on the FDA's untruthfulness, those claims must be dismissed. Id.

O R D E R

IT IS, THEREFORE, ORDERED, that Defendants' Motion to Substitute and Amend [Doc. 12] is **GRANTED**, and the United States of America is substituted as Defendant on those claims. The claims against Defendants Chazin, Catterson, and Sharpless are hereby **DISMISSED WITH PREJUDICE.**

IT IS FURTHER ORDERED that the Defendants' Motion to Dismiss [Doc. 13] is **GRANTED**, and the Plaintiff's claims against the FDA Office of Generic Drugs and the United States related to (1) the FDA's approval of Sumatriptan and (2) the FDA's alleged failure to provide truthful information are hereby **DISMISSED WITHOUT PREJUDICE** on the grounds of sovereign immunity. The Plaintiff's negligence claims regarding the testing performed by the FDA are **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED.

Signed: August 27, 2021

Martin Reidinger
Chief United States District Judge